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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,816	04/09/2004	Ara Hovanessian	02356.0091	9491

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/820,816	HOVANESSIAN ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-57* is/are pending in the application.

4a) Of the above claim(s) *57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 1, 2007 in response to the Office Action of August 1, 2006 is acknowledged and has been entered. Claims 1-32 have been canceled, and claims 33-57 have been added. New claim 57, drawn to a method of monitoring SIV infection in a monkey is withdrawn for being drawn to a non-elected invention. Claims 33-56 are currently examined.

Election/Restrictions

Applicant requested clarification with respect to claims 12 and 27. Claim 12, which is presently canceled, was examined in the Office action of August 1, 2006. Claim 27 was withdrawn for being drawn to a non-elected invention. It is noted that the current claims are examined with respect to the originally elected sequences such as SEQ ID NO: 2, 4, and 5.

Claim Objections

The objection to claims 5, 6, 8, 9 and 26 **is moot** because Applicant canceled the claims.

Claims 33-56 and the specification are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID NOs to all sequences in the specification and the claims (See 37 C.F.R. § 1.821(d)). For example the sequence: LEQIWNNMTWMQWDK in claims 33-35, 46, 47 lacks SEQ ID identifier. It is understood that "[SEQ ID NO: 1]" means that the claim is amended to take out "SEQ ID NO: 1". Additionally the sequences and their SEQ ID identifiers recited in the claims and the specification must be identical with SEQ ID identifiers as listed in the sequence listing. Presently SEQ ID NO: 2 recited in the claims is <u>not</u> identical with SEQ ID NO: 2 listed in the sequence listing. For this reason a meaningful sequence search cannot be performed. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 14 **is moot** because Applicant canceled the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1-9, 12-16, 26, 28, and 32 under 35 U.S.C. 112, first paragraph **is moot** because Applicant canceled the claims.

Claims 33-56 (which are drawn to the same invention as canceled claims 1-9, 12-16, 26, 28, and 32) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection of the subject matter of claims 1-9, 12-16, 26, 28, and 32, now presented in claims 33-56, is of record in the previous Office action.

Canceled claims 1-9, 12-16, 26, 28, and 32 were rejected because of the lack of an adequate written description for the claimed pharmaceutical composition and vaccine comprising peptide variants having 90 to 99.99999% homology to SEQ ID NOs: 1-9. It is acknowledged that the new claims 33-56 do not recite peptide variants having 90 to 99.99999% homology to

SEQ ID NOs: 1-9. Although the current claims do not recite "peptide variants" the claims are drawn to a large number of peptides. The current claims require that all peptides encompassed by the claims will elicit antibodies against CBD-1 peptide: LEQIWNNMTWMQWDK. As discussed in the rejection of record in the Office action of August 1, 2006, the teachings of the art indicate that all currently claimed peptides will not effectively elicit antibodies with specificity to CBD-1 peptide: LEQIWNNMTWMQWDK. For this reason the claimed peptide structures lack the functional correlation. At the time when the current application was filed Applicant was not in possession of all peptides and peptide variants currently claimed. Therefore the present amendment does not overcome the written description rejection and thus the rejection is maintained.

Rejection of claims 1-9, 12-16, 26, 28, and 32 under 35 U.S.C. 112, first paragraph, for lack of an adequate enablement **is moot** because Applicant canceled the claims.

Claims 33-56 (which are drawn to the same invention as canceled claims 1-9, 12-16, 26, 28, and 32) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of the subject matter of claims 1-9, 12-16, 26, 28, and 32, now presented in claims 33-56, is of record in the previous Office action.

Canceled claims 1-9, 12-16, 26, 28, and 32 were rejected because of the lack of an adequate enablement for the claimed pharmaceutical composition and vaccine comprising peptide variants having 90 to 99.99999% homology to SEQ ID NOs: 1-9. It is acknowledged that

the new claims 33-56 do not recite peptide variants having 90 to 99.99999% homology to SEQ ID NOs: 1-9. It is also acknowledged that the present claims do not recite "vaccines". However because the claims are drawn to a pharmaceutical composition comprising a large number of peptides and because the current specification does not provide an adequate enablement for the presently claimed composition to be used as a pharmaceutical, the claims stand rejected as further discussed below.

The working examples in the current specification provide evidence that immunization of rabbits with the CBD-1 peptide: LEQIWNNMTWMQWDK resulted in generation of anti-CBD-1 specific antibodies (see Example 7). The anti-CBD-1 specific antibodies generated in rabbits were shown to inhibit the HIV-1 infection of T lymphocytes (MT4 lymphocytic cell line) in the in vitro cell culture (see Examples 8-12). The antibodies were also shown to inhibit HIV-1 infection of the primary PBMC derived CD4+ T lymphocytes in vitro (see Example 16). Example 18 discusses that macaques immunized with SEQ ID NO: 1 to 18 show reduction of the in vivo SIV infection. It is noted that a figure representing the results of the in vivo studies discussed in Example 18 is not present in the drawings or the specification. In view of the Examples presented in the current specification it is acknowledged that the CBD-1 peptide: LEQIWNNMTWMQWDK has immunogenic/antigenic properties as evidenced by the generation of the anti-CBD-1 specific antibodies in rabbits. It is also acknowledged that the anti-CBD-1 antibodies are effective in inhibiting HIV-1 infection in MT4 lymphocytic cell line in vitro. The current specification contemplates using the claimed composition as vaccine for immunotherapy to prevent and/or treat HIV-infection in humans (see page 8). The recitation of pharmaceutical composition in the claims implies that Applicant intends that the present

composition will have a therapeutic effect when administered to humans. As discussed above the specification does not provide an enabling disclosure for the large number of peptides to be used as pharmaceuticals for treatment of HIV infection in humans. The skilled artisan would require an undue amount of experimentation in order to accurately extrapolate that all peptides encompassed by the current claims could be successfully used as therapeutics. The unpredictability in the art of HIV treatment is discussed in the enablement rejection of record in the Office action of August 1, 2006. Thus in view of the of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention in its full scope. For this reason the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of 35 U.S.C. 102(b) which forms the basis for all rejections under this section made in this office action set forth in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 1-4, and 12-14 under 35 U.S.C. 102(b) as being anticipated by Berman et al., (US Patent 6,042,836, herein Berman) **is withdrawn** in view of Applicants amendment and arguments. The claims presently recite the closed language with respect to the peptides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 1, 4, 12-16, and 28 under 35 U.S.C. 103(a) as being unpatentable over Dong et al., (Immunology Letters, 2001, herein Dong) in view of Rubinstein et al., (US Patent 6,447,778, herein Rubinstein) **is withdrawn** in view of Applicants amendment and arguments. The claims presently recite the closed language with respect to the peptides.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

4/27/07

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600